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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,034	01/03/2001	Jouko Savolainen	81757.0029	9155
26021	7590	11/26/2003	EXAMINER	
HOGAN & HARTSON L.L.P. 500 S. GRAND AVENUE SUITE 1900 LOS ANGELES, CA 90071-2611			MOHAMED, ABDEL A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/674,034

Applicant(s)

SAVOLAINEN, JOUKO

Examiner

Abdel A. Mohamed

Art Unit

1653

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-18.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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Continuation of 5. does NOT place the application in condition for allowance because: The rejection under 35 U.S.C.103(a) over the prior art of record is maintained. It is noted that Applicant has not amended the claims and Applicant's arguments are basically the same as the arguments filed on 5/5/03 (Paper No. 10). Thus, the Examiner reiterates the previous Office action. Applicant's arguments that the cited references cannot render claim 1 obvious, because the cited references fail to teach or suggest a method for modification and isolation of a protein comprising: mixing whey or soy proteins with sulfite forming reagent under a condition to sulfonate the protein without using an oxidizing agent, precipitating the proteins, and recovering the proteins is unpersuasive. Contrary to Applicant's arguments, WO 95/22907 teaches a method for modification and isolation of protein from whey comprising a) whey or a concentrate thereof, a reagent which forms sulfite ions, and an oxidant are brought into contact in order to sulfonate, b) the sulfonated and oxidized whey protein is precipitated out from the whey or concentrate thereof at an acid pH, and c) the precipitated sulfonated and oxidized whey protein is recovered from the product mixture and possibly subjected to an after-treatment (See e.g., page 1 lines 4-14). The precipitation step b) preferably carried out by using a pH value of approximately 2.5-6.5, and most preferably a pH value of 3.0-5.0. After the pH adjustment of step b), the temperature is adjusted to be sufficiently high, preferably within the range 25-55 degrees Centigrade, most preferably within the range 30-50 degrees Centigrade. The protein content of the whey concentrate is 2-7% and the dry weight of the concentrate is 11-12%. The sulfonation in a) employs the sulfite as Na<sub>2</sub>HSO<sub>3</sub>, Na<sub>2</sub>SO<sub>5</sub> or Na<sub>2</sub>SO<sub>3</sub> and is used at the concentration in an amount of 0.02-0.20 M, preferably 0.05-0.1 M (See e.g., page 9, lines 30 to page 10, lines 8; page 11, lines 34 to page 12 lines 26; claims 1-2, 4 and 7-8). The primary reference of WO 95/22907 differs from claims 1-18 in not teaching the sulfonation of the whey protein without using oxidizing agent (i.e., omitting the oxidation step in the claimed process). Although, on pages 5-6, the primary reference discloses the advantages and disadvantages of using oxidative sulfitolysis with the purpose of isolating proteins from whey wherein the oxidant being oxygen and the catalyst a Cu<sup>++</sup> ion as CuCO<sub>3</sub>. Based on oxidative sulfitolysis, the result either did not aim at providing a method of isolation but only a method of modifying certain properties, or the method is so difficult to exploit on an industrial scale that it cannot be implemented. Thus, the primary reference clearly suggests that the use of oxidizing agent would decrease the yield of the product desired in large-scale production. Further, the secondary reference of Petruccelli et al., teaches the partial reduction of disulfide bonds of soy protein isolates in which the addition of catalyst (Cu) and oxygen showed a similar effect in the sulfitolysis of soy proteins with Na<sub>2</sub>SO<sub>3</sub>. (See e.g., abstract). On page 2006, the reference clearly shows that in the presence of a catalyst (Cu) and/or an oxidizing agent (O<sub>2</sub>), the AB-11S subunits is not completely reduced, probably because the reducing agent is unable to reach all SS bonds. Reduction of soy protein isolates with sodium sulfite affects different subunits according to the reaction conditions employed; namely, mostly AB dimers are reduced if urea is used, whereas if Cu or O<sub>2</sub> is employed, mainly components other than AB-11S undergo change. The reference continues by stating that to obtain complete sulfitolysis, both urea and C or O<sub>2</sub> are required. The reference concludes by stating that the addition of a catalyst (Cu) and oxidizing agent (O<sub>2</sub>) affects similarly the sulfitolysis of soy proteins with Na<sub>2</sub>SO<sub>3</sub>; the simultaneous presence of both agents is not required. Thus, clearly showing that without using an oxidizing agent that one of ordinary skill in the art would be able to obtain complete sulfitolysis in a method for modification and isolation of proteins from whey or soy. With respect to Applicant's arguments on page 4, last paragraph on the remarks filed 10/20/03 that Petruccelli (the secondary reference) concludes that the presence of oxidizing agent is needed to achieve complete sulfitolysis (abstract and page 2006, second paragraph under CONCLUSIONS) is not persuasive. Although, in the abstract Petruccelli states that to achieve a complete sulfitolysis, the presence of a denaturing and an oxidizing agent were needed; however, contrary to Applicant's arguments and as discussed in the above paragraph, the reference clearly states on page 2006, third paragraph under CONCLUSIONS that this isolate, (i.e., soy protein isolate) in spite of having a high percentage of reduced SS bonds, only has 20% reduction of the AB subunit of glycin. Treatment with Na<sub>2</sub>SO<sub>3</sub> lead to only 10 % reduction, whereas a concentration 100 times higher increases that percentage to 40 % (at 7 h and in the absence of either denaturing or oxidizing agents). Thus, clearly showing and/or motivating that without using an oxidizing agent that one of ordinary skill in the art would be able to obtain complete sulfitolysis in a method for modification and isolation of proteins from whey or soy. Further, claim 11 does not exclude and/or omit the oxidation step in the claimed process as argued by Applicant. With respect to Applicant's argument that the sulfitolysis of '907 patent occurs in 10-50 minutes (the '907 patent, page 8, lines 3-4). The sulfitolysis of Petruccelli occurs in 15 hours if neither copper nor O<sub>2</sub> is employed (Petruccelli, page 2006, column 1, third paragraph under CONCLUSIONS). A person of ordinary skill in the art would not be motivated to increase reaction times from 10-50 minutes to 15 hours. Consequently, a person of ordinary skill in the art would not be motivated to combine these references is unpersuasive because Applicant's arguments is directed to the limitations (i.e., reaction time) that are not recited in the claims. Thus, the arguments is irrelevant since it is reflected on the limitations that are not recited in the claim(s). Therefore, in view of the above and in view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated at the time the invention was made to employ a method for modification and isolation of a protein such as whey or soy protein by sulfonating the protein without using an oxidizing agent and then precipitating the sulfonated protein at acidic pH and recovering thereof in the manner claimed in claims 1-18; which fall within the scope of the combined teachings of the prior art method would have been prima facie obvious from said prior art disclosure to a person of ordinary skill in the art because as held in host of cases including *Ex parte Harris*, 748 O.G. 586; *In re Rosselet*, 146 USPQ 183; *In re Burgess*, 149 USPQ 355 and as exemplified by *In re Betz*, "the test of obviousness is not express suggestion of the claimed invention in any and all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them". Thus, the rejection of claims 1-18 under 35 U.S.C. 103(a) over the prior art of record is maintained for the same reasons discussed in the previous Office action.